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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/879,279 | 06/12/2001 | Gayle Dace | 45163-1005 | 3524 |

22847 7590 07/13/2004

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| EXAMINER | |
|---|---|
| EPPERSON, JON D | |
| **ART UNIT** | **PAPER NUMBER** |
| 1639 | |

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/879,279 | DACE ET AL. | |
| | Examiner | Art Unit | |
| | Jon D Epperson | 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *9,10,16,17,22 and 25-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-15,18-21,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on April 21, 2004.

### *Status of the Claims*

2. Claims 1-30 were present. Applicants subsequently added claim 31 in the 1/7/2004 Response. Therefore, claims 1-31 are currently pending.

3. Applicant's response to the Restriction and/or Election of Species requirements in the April 21, 2004 Response is acknowledged (Applicant elected ***without traverse*** Group I, i.e., claims 1-8, 11-24 and 31) and claims 9-10 and 25-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

4. Please note: Applicant's elected species (Subgroup I = 5'-$(CA)_6$-3'; Subgroup III = biotin; Subgroup IV = streptavidin; Subgroup V = magnetic bead separation; Subgroup VI = alkaline buffer at pH = 9.5; subgroup VII = plasmid library) was found in the art. Furthermore, Applicant's *specifically* elected species (Subgroup II = 3 biotinylated $(GT)_6$-5'-bicyclic structure wherein LNA occurs at ALL positions) was searched and was not found in the prior art. Thus,

the search was expanded to non-elected species, which *were* found in the prior art, see rejections below. Also, see MPEP § 803.02 (emphasis added):

> On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. ***The prior art search, however, will not be extended unnecessarily to cover all nonelected species.*** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

5. Claims 16-17, 22 and 31 are withdrawn (**Please note**: claim 22 does not read on the elected "Subgroup IV = streptavidin" species as purported because streptavidin is not listed in the Markush group; **Please also note**: claim 31 does not read on the elected species as purported because Applicants amended their elected species to include a modified oligonucleotide wherein "ALL the nucleotides are LNA, and NOT that just the first G in LNA", which would not read on claim 31 wherein ONLY the first G is an LNA e.g., compare see 1/22/2004 Response, page 6, last paragraph to claim 31) from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species (see below i.e., ***Response to Restriction and/or Election of Species***).

6. Therefore, claims 1-8, 11-15, 18-21 and 23-24 are examined on the merits in this action.

***Response to Restriction and/or Election of Species***

7. Applicant's election of Group I (claims 1-9 and 17-19) **without traverse** in 4/21/2004 Response is acknowledged (see also 1/22/2004, 1/7/2004 and 10/20/2003 Responses).

8. Applicant's election of species in 4/21/2004 Response is also acknowledged (see also 1/22/2004, 1/7/2004 and 10/20/2003 Responses). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has also been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)).

9. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

***PTO-892 Form***

10. If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application

is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

### *Information Disclosure Statement*

11. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.

### *Specification*

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Claims Rejections - 35 U.S.C. 112, second paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 7, 11 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. ***Claims 1 and 7*** recite "substantially" all. The term "substantially" is a relative term, which renders the claim indefinite and/or unclear. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also MPEP § 2173.05(b).

B. For **claim 7**, the phrase "reaction conditions at which substantially all of the targeted simple sequence repeats form a strand displacing 'A' helix" is vague and indefinite. For example, it is not clear what the "reaction conditions" promote the formation of an "A helix" because Applicants' specification does not state which parameters are critical in this regard. Therefore, the metes and bound of the claimed invention cannot be determined.

C. **Claim 11** recites the limitation "the insert in the 3.5 kb clone" in the last line. There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 1 and all dependent claims are rejected under 35 USC 112, second paragraph.

D. **Claim 24** recite the limitation "the linking molecule biotin" and "the modified oligonucleotides" in line 10. There is insufficient antecedent basis for these limitations in the claim.

***Claims Rejections - 35 U.S.C. 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-8, 12-15, 18-21, 23-24 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakobsen et al. (US Pub. No. 2003/0077609 A1) (Priority to 60/278,598, filed on **March 25, 2001**) and Cregan et al. (Cregan, P.B.; Mudge, J.; Fickus, E.W.; Marek, L.F.; Danesh, D.; Denny, R.; Shoemaker, R.C.; Matthews, B.F.; Jarvik, T.; Young, N.D. "Targeted Isolation of Simple Sequence Repeat Markers through the use of Bacterial Artificial Chromosomes" *Theor. Appl. Genet.* **1999**, *98*, 919-928) and Sambrook et al. (Sambrook J. and Russell, D.W. Molecular Cloning: A laboratory Manual. New York: Cold Spring Harbor

Laboratory. **January 15, 2001**, Vol. 2, pages 11.35 and 11.98-11.106) and Brown (Brown, T.A. Genomes. New York: John Wiley & Sons, Inc. **1999**, pages 18-23 and 136-137).

For ***claim 1***, Jakobsen et al. (see entire document) disclose methods for using modified "locked nucleic acids" (LNAs) for "the isolation, purification, amplification, detection, identification, quantification, or capture of nucleic acids" including applications in gene mapping and/or genotyping (e.g., see Jakobsen et al., abstract; see also page 4, paragraph 43, see also page 6, paragraph 63), which reads on claim 1. For example, Jakobsen et al. disclose providing one or more modified oligonucleotide conjugates, wherein each of the modified oligonucleotide conjugates comprises at least one locked nucleic acid and a linking molecule (e.g., see Jakobsen et al., paragraph 14 wherein LNAs are disclosed; see also paragraph 49 wherein Applicants' elected "biotin" species is disclosed; see especially page 7, Example 2, see also paragraph 76; see also paragraphs 53-63). In addition, Jakobsen et al. disclose incubating a sample of nucleic acids with the modified oligonucleotide conjugates, thereby forming one or more hybridized duplexes (e.g., see Jakobsen et al., page 7, Example 2 wherein the "locked" modified oligonucleotide conjugates were used to "hybridize" to a sample of 5' biotin-labeled 50-mer or 30-mer oligonucleotide, each encompassing 1 to 5 SNPs [single nucleotide polymorphisms] for SNP genotyping; see also page 6, paragraph 55, "In a further aspect, oligonucleotides of the invention may be used to construct new affinity pairs ... The affinity pairs may be used in ... capture and detection of a diversity of the target molecules"; see also paragraph 63, "Assay using an immobilized array of nucleic

acid sequences may be used for determining the sequence of an unknown nucleic acid; single nucleotide polymorphism (SNP) analysis; analysis of gene expression patterns from a particular species, tissue, cell type, etc.; gene identification"). Jakobsen et al. further disclose contacting substantially all of the hybridized duplexes with a linking source, such that the linking molecule of each duplex that contacts the linking source forms a bond with the linking source (e.g., see page 7, Example 2, especially paragraph 76 wherein Applicants' elected "streptavidin" species is disclosed). Finally, Jakobsen et al. disclose separating substantially all of the hybridized duplexes from the sample of nucleic acids (e.g., see page 7, Example 2, especially washing steps).

For ***claim 7***, Jakobsen et al. do not explicitly state that an "A" helix is formed but the Examiner contends that an "A" helix must inherently be formed because Jakobsen et al. use the same LNAs for hybridization as are claimed by Applicants (e.g., see page 4, paragraph 39 of Applicants' specification which states that the use of a LNA will produce an "A" helix. No other reaction conditions are discussed for forming an "A" helix). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For ***claim 18***, Jakobsen et al. disclose complementary sequences (e.g., see Jakobsen et al., page 1, paragraph 11; see also page 7, Example 2, paragraph 75).

For ***claim 19***, Jakobsen et al. disclose biotin bound to 5' end (e.g., page 7, Example 2, paragraph 76; see also page 3, column 1, paragraph 28; see also page 5, paragraph, column 1, paragraph 49).

For ***claim 20***, Jakobsen et al. disclose biotin (e.g., see page 7, Example 2, paragraph 76).

For ***claim 21***, Jakobsen et al. disclose streptavidin (e.g., see page 7, Example 2, paragraph 76)

The prior art teachings of Jakobsen et al. differ from the claimed invention as follows:

For ***claims 1-2, 18 and 24***, the Jakobsen et al. reference is deficient in that it does not specifically recite the use of "simple sequence repeat" (SSR) target molecules. Although, Jakobsen et al. teach the use of target molecules like SNPs as physical markers in gene mapping and/or genotyping experiments (e.g., see page 7, Example 2; see also page 6, paragraph 63), Jakobsen et al. fail to explicitly refer to other types of physical markers like SSR target molecules. In addition, Jakobsen et al. fail to teach the use of "extraction" techniques including the application of streptavidin-coated magnetic beads. Jakobsen et al. only teach the use of biotin/streptavidin in conjunction with microarray slides (e.g., see page 7, Example 2).

For ***claim 3***, Jakobsen et al. fail to teach the use of SSR portion comprising 1, 2, 3 or 4 base repeats.

For ***claims 4-6***, Jakobsen et al. fail to teach the use of alkaline buffer for the dissociation of the target molecule in the range of pH 9-10.

For ***claim 8***, Jakobsen et al. fail to teach the formation of a new library that is enriched in the targeted SSRs.

For ***claims 12-15***, Jakobsen et al. fail to teach double stranded circular DNA plasmid libraries.

For ***claim 21***, Jakobsen et al. fail to teach streptavidin-coated beds.

For ***claim 23***, Jakobsen et al. fail to teach the use of a magnet.

For ***claim 24***, Jakobsen et al., fails to teach the use of streptavidin-coated magnetic beads, incubating at pH of around 9.5 for dissociation, transforming the simple sequences into *E. coli* and sequencing the repeats.

However, the combined references of Cregan et al. Sambrook et al. and Brown teach the following limitations that are deficient in Jakobsen et al.:

For ***claims 1-2 and 24***, the combined references of Cregan et al., Sambrook et al., and Brown (see entire documents) teach the use of SSRs as target molecules (e.g., see Cregan et al., abstract; see also Brown, page 136, "Mini- and microsatellites" section). Furthermore, the use of "extraction" techniques including the application of streptavidin-coated magnetic beads is also taught (e.g., see Sambrook et al., page 11.99, figure 11-20).

For ***claim 3***, the combined references of Cregan et al., Sambrook et al., and Brown also teach the use of SSR portion comprising 1, 2, 3, or 4 base repeats (e.g., see Brown, page 136, column 2, last paragraph wherein CACACACACACACACA is exemplified i.e., a "2 base repeat"; see also Cregan et al., page 919, column 2, last paragraph wherein CA, ATT and ATGT are disclosed i.e., 2, 3 and 4 base repeats).

For ***claims 4-6***, the combined references of Cregan et al., Sambrook et al., and Brown teach the use of alkaline buffer to dissociate the target molecules (e.g., see page 11.104, step 13 a-b). The combined references do not explicitly teach the use of pH = 9-10, but they do teach the addition of a strong base (i.e., 0.1 M NaOH, pH = 13), which would be expected to produce pH ranges between 9-10 when combined with other more acidic components (e.g., the sample and/or sample buffer i.e., pH < 9-10). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For ***claim 8***, the combined references of Cregan et al., Sambrook et al., and Brown teach the formation of a new library enriched in SSRs (e.g., see Cregan et al., page 921, middle paragraph, "Selected colonies were picked onto microtiter plates followed by two additional cycles of screening and purification"; see also Sambrook et al., page 11.98, paragraphs 2-3).

For ***claims 12-15***, the combined references of Cregan et al., Sambrook et al., and Brown teach double stranded circular DNA plasmid libraries (e.g., see Cregan et al., page 921, middle paragraph; see also Sambrook et al., figure 11-20).

For ***claim 21***, the combined references of Cregan et al., Sambrook et al., and Brown teach streptavidin-coated beads (e.g., see Sambrook et al., page 11.99, figure 11-20).

For ***claim 23***, the combined references of Cregan et al., Sambrook et al., and Brown teach the use of streptavidin-coated paramagnetic beads (e.g., see Sambrook et al., page 11.99, figure 11-20).

For ***claim 24***, the combined references of Cregan et al., Sambrook et al., and Brown teach the use of streptavidin-coated magnetic beads (e.g., see Sambrook et al., page 11.99, figure 11-20), incubating at pH of around 9.5 for dissociation (see section for ***claims 4-6*** above), transforming the simple sequences into *E. coli* (e.g., see Cregan et al., page 921, paragraph 1) and sequencing the repeats (e.g., see Cregan et al., page 921, last paragraph).

It would have been obvious to one skilled in the art at the time the invention was made to capture "simple sequence repeats" (SSRs) via "streptavidin-coated magnetic beads" as taught by the combined references of Cregan et al., Sambrook et al., and Brown using "locked nucleic acids" (LNAs) as taught by Jakobsen et al. because Jakobsen et al. teach that LNAs possess enhanced specificity/affinity for target sequences and thus can be used to improve all hybridization reactions and specifically point to the PCR based characterization of physical markers commonly used in gene mapping and/or genotyping experiments (e.g., see Jakobsen et al., page 6, paragraph 63; see especially page 7, Example 2), which would encompass the physical markers exemplified by the combined references of Cregan et al., Sambrook et al., and Brown (i.e., the references represent

analogous art because "simple sequence repeats" (SSR) and "single nucleotide polymorphisms" (SNP) markers are both PCR-based, co-dominant and abundant molecular markers from eukaryotic genomes that are being widely used in genetic mapping, phylogenetic studies and marker-assisted selection) (e.g., see Brown, pages 18-22 for background information on the use of SNPs and SSRs). In addition, Cregan et al. state that the bacterial artificial chromosomes (BACs) used to isolate SSR markers "can readily be extended to other types of DNA markers, including single nucleotide polymorphisms [i.e., SNPs]" (e.g., see Cregan et al., page 919, column 2, paragraph 1), which would encompass the SNPs disclosed by Jakobsen et al. A person of skill in the art would have been motivated to use the LNAs to search for SSRs because Cregan et al. state that LNAs provide "enhanced hybridization and [PCR] priming properties" (e.g., see Cregan et al., page 1, paragraph 10; see also page 1, paragraph 11 wherein beneficial PCR results are also disclosed), which would increase the efficiency of searching for the SSRs (just as they do for SNPs) because the SSRs represent PCR-based markers that require hybridization and PCR priming (e.g., see Cregan et al., page 919, column 2, last paragraph). Furthermore, SSRs represent a "preferred embodiment" of physical markers for gene mapping and/or genotyping (e.g., see Cregan et al., page 919, column 2, last paragraph, "The high level of informativeness and co-dominance of microsatellite markers, their widespread occurrence in eukaryotic genomes, and easy amplification via standard PCR technology, make SSR the current marker of choice [i.e., a preferred embodiment] in many species"; see also Brown, page 21, column 1, "Microsatellites [SSRs] are more popular ... [because they] are more conveniently spaced through the

genome. Second, the quickest way to type a length polymorphism is by PCR, but PCR typing is much quicker and more accurate with sequences less than 300 bp in length [i.e., SSRs]; see also page 21, column 2, wherein the drawbacks of SNPs are outlines e.g., they have only two alleles; see also pages 136-137, "Mini- and microsatellites" section). Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Cregan et al. state that their BAC technology will work with both SNPs and SSRs and Sambrook et al. state that their streptavidin-coated magnetic beads are particularly well suited for selecting large genomic DNA clones using BACs (see Cregan et al., page 919, column 2, paragraph 1, "This targeted approach to identifying new DNA markers [i.e., SSRs] can readily be extended to ... single nucleotide polymorphisms"; see also Sambrook et al., page 11.98-11.100, especially figure 11-20).

***Double Patenting***

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-8, 11-15, 18-21 and 23-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent Application No. US 2003/0032028 A1 (referred to herein as '028).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986).

The conflicting claims are not patentably distinct from each other because the claims of the '028 and the claims of the present application are both drawn to the same methods for capturing target sequences that include single sequence repeats. For example, both references disclose **[a]** an in vitro method for capturing target sequences (e.g., compare claim 1 of the present application to claim 1 of '028), **[b]** the use of simple sequence target repeats (e.g., compare claim 1 of the present application to claims 1 and 29 of '028), **[c]** providing modified oligonucleotide conjugates that comprise at least one locked nucleic acid and a linking molecule (e.g., compare claim 1 of the present application to claims 1, 8 and 11 of '028), **[d]** incubating a sample of nucleic acids with modified oligonucleotide conjugates thereby forming one or more hybridized duplexes (e.g., compare claim 1 of the present application to claim 1 of '028), **[e]** contacting substantially all of the hybridized duplexes with a linking source such that the linking molecule of each duplex that contacts the linking source forms a bond with the linking source (e.g., compare claim 1 of the present application to claim 1 of '028), **[f]** separating substantially

all of the hybridized duplexes from the sample of nucleic acids by extracting the linking source from the sample (e.g., compare claim 1 of the present application to claim 1 of '028). In addition both Applications disclose **[g]** simple sequence repeats with 1, 2, 3, or 4 base repeats (e.g., compare claims 2-3 of the present application with claims 29-30 of '028), **[h]** the use of alkaline buffer at pH between 9 and 10 (e.g., compare claims 4-6 of the present application to claims 3-4 of '028), **[i]** the formation of an "A" helix (e.g., compare claim 7 of the present application to claim 5 of '028), **[j]** the use of a 3.6 kb clone (e.g., compare claim 11 of the present application to claim 17 of '028), **[k]** the use of a double stranded DNA plasmid library (e.g., compare claims 13-15 of the present application to claims 18-20 of '028), **[l]** a linking molecule with biotin bound to a 5' end (e.g., compare claim 19 of the present application to claim 23 of '028), **[m]** a linking molecule that comprises antibody, biotin, streptavidin-coated beads (e.g., compare claims 20-22 of the present application to claims 24-26 of '028), **[n]** the use of a magnet (e.g., compare claim 23 of the present application to claim 27 of '028) and **[o]** the use of transforming E. coli and sequence the transformed simple sequences (e.g., compare claim 24 of the present application to 33 of '028).

It would have been obvious to combine the claims of '028 to render obvious the claims of the present application because the claims of '028 teach a generic system for capturing one or more target sequences (i.e., claim 1 of '028 is broader in scope and would encompass all embodiments of claim 1 in the present application) and then further teaches more specific embodiments that teach toward applicants' claimed invention (see above analysis).

This is a provisional obviousness-type double patenting rejection.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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July 5, 2004